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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,021	12/21/2001	Yasumichi Hitoshi	7946-79823-01	6123

74839 7590 12/27/2007

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121 SW Salmon St
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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/026,021	HITOSHI ET AL.	
	Examiner	Art Unit	
	MISOOK YU	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10,24,25,32-34 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 10, 24, 25, 32-34, and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 9, 10, 24, 25, 32-34, and 36-38 are pending and under consideration.

Claim Rejections - 35 USC § 103, Maintained

Claims 9, 10, 24, 25, 32, 33, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,650,501 A of record in WO 01/53312 (Tang) A1 of record.

Claims 9, 10, 24, 25, 32, 33, 36, and 37 are drawn to method of identifying a compound that modulates cellular proliferation by measuring kinase activity of SAK polypeptide when said compound is contacted with a SAK polypeptide encoded by a nucleic acid encoding a SAK polypeptide having at least 95% sequence identity to instant SEQ ID NO:2 protein, wherein the kinase is measured in vitro (claim 10), the modulation is inhibition of cellular proliferation (claim 24), the polypeptide being recombinant (claim 32), wherein the compound is an antibody (claim 34), wherein the polypeptide in the base claim is encoded by **a** sequence of SEQ ID NO: 1, or a small organic molecule (claim 36), or a peptide (claim 37).

Applicant argues that 47% sequence similarity in the catalytic domain of a putative kinase in the absence of biochemical confirmation of kinase activity is insufficient to demonstrate that a particular amino acid sequence has kinase activity. Applicant argues that Examiner's analysis of the SAK protein of the '501 patent having kinase activity depends on impermissible hindsight.

These arguments have been fully considered but found unpersuasive because The '501 patent teaches a SAK polypeptide having at least 77% sequence identity to instant SEQ ID NO:2 protein as shown by the sequence alignment below.

```
RESULT 1
US-08-252-995D-4
; Sequence 4, Application US/08252995D
; Patent No. 5650501
;  GENERAL INFORMATION:
;    APPLICANT:  Dennis, James W
;    APPLICANT:  Heffernan, Mike
;    APPLICANT:  Fode, Carol
;    TITLE OF INVENTION:  NOVEL SERINE/THREONINE KINASE
;    NUMBER OF SEQUENCES:  14
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  BERESKIN & PARR
;      STREET:  40 King Street West
;      CITY:  Toronto
;      STATE:  Ontario
;      COUNTRY:  Canada
;      ZIP:  M5H 3Y2
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Floppy disk
;      COMPUTER:  IBM PC compatible
;      OPERATING SYSTEM:  PC-DOS/MS-DOS
;      SOFTWARE:  PatentIn Release #1.0, Version #1.30
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/252,995D
;      FILING DATE:  02-JUN-1994
;      CLASSIFICATION:  536
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Kurdydyk, Linda M
;      REGISTRATION NUMBER:  34,971
;      REFERENCE/DOCKET NUMBER:  3153-96
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (416) 364-7311
;      TELEFAX:  (416) 361-1398
;  INFORMATION FOR SEQ ID NO:  4:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  925 amino acids
;      TYPE:  amino acid
;      TOPOLOGY:  linear
;    MOLECULE TYPE:  protein
US-08-252-995D-4

  Query Match             77.3%;  Score 3927.5;  DB 1;  Length 925;
  Best Local Similarity   78.6%;  Pred. No. 8.6e-297;
  Matches  763;  Conservative   76;  Mismatches   83;  Indels   49;  Gaps    9;
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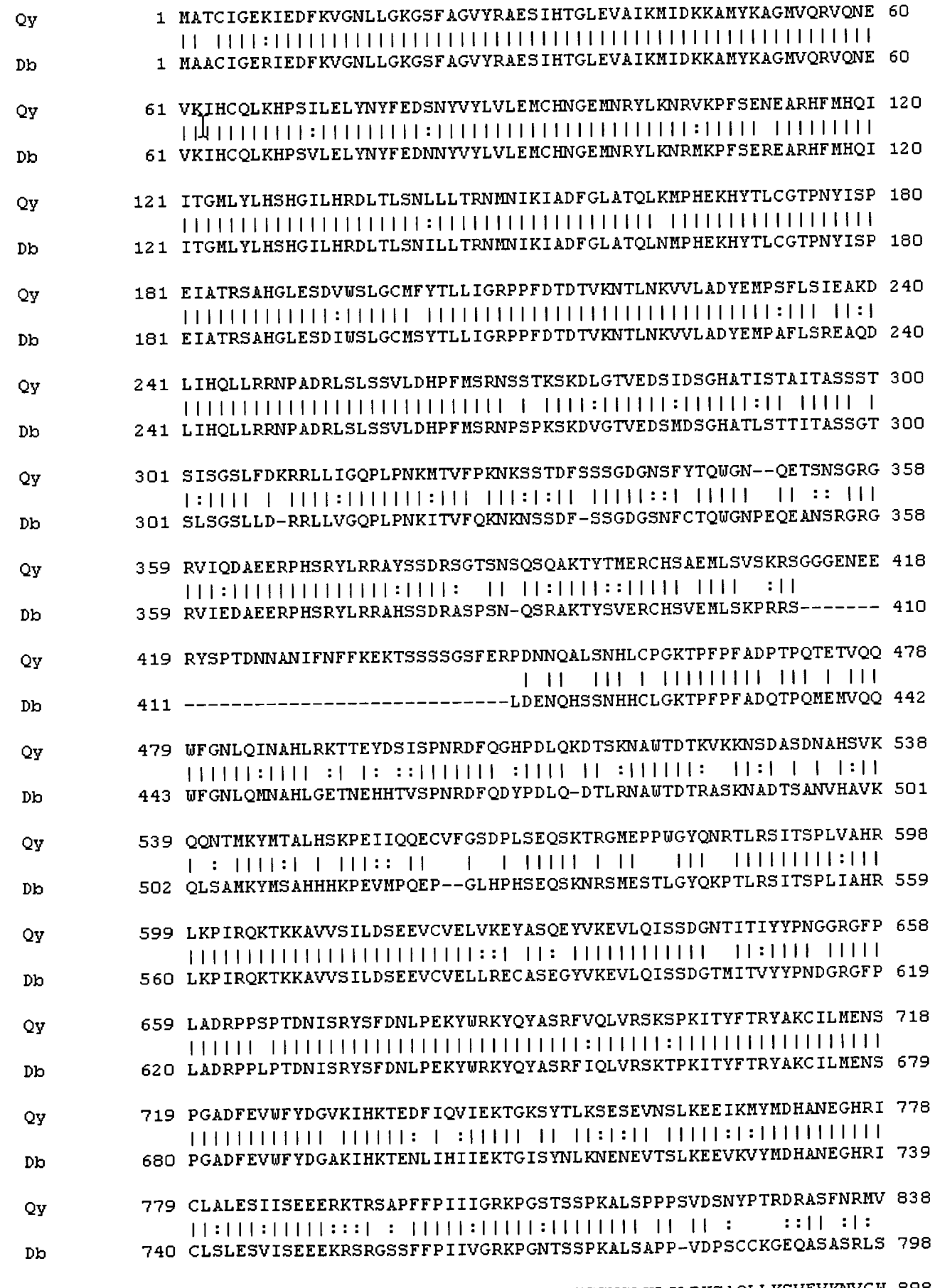
Qy 1 MATCIGEKIEDFKVGNLLGKGSFAGVYRAESIHTGLEVAIKMIDKKAMYKAGMVQRVQNE 60
Db 1 MAACIGERIEDFKVGNLLGKGSFAGVYRAESIHTGLEVAIKMIDKKAMYKAGMVQRVQNE 60
Qy 61 VKIHCQLKHPSILELYNYFEDSNYVYLVLEMCHNGEMNRYLKNRVKPFSENEARHFMHQI 120
Db 61 VKIHCQLKHPSVLELYNYFEDNNYVYLVLEMCHNGEMNRYLKNRMKPFSEREARHFMHQI 120
Qy 121 ITGMLYLHSHGILHRDLTLSNLLLTRNMNIKIADFGLATQLKMPHEKHYTLCGTPNYISP 180
Db 121 ITGMLYLHSHGILHRDLTLSNILLTRNMNIKIADFGLATQLNMPHEKHYTLCGTPNYISP 180
Qy 181 EIATRSAHGLESDVWSLGCMFYTLLIGRPPFDTDTVKNTLNKVVLADYEMPSFLSIEAKD 240
Db 181 EIATRSAHGLESDIWSLGCMSYTLLIGRPPFDTDTVKNTLNKVVLADYEMPAFLSREAQD 240
Qy 241 LIHQLLRRNPADRLSLSSVLDHPFMSRNSSTKSKDLGTVEDSIDSGHATISTAITASSST 300
Db 241 LIHQLLRRNPADRLSLSSVLDHPFMSRNPSPKSKDVGTVEDSMDSGHATLSTTITASSGT 300
Qy 301 SISGSLFDKRRLLIGQPLPNKMTVFPKNKSSTDFSSSGDGNSFYTQWGN--QETSNSGRG 358
Db 301 SLSGSLLD-RRLLVGQPLPNKITVFQKNKNSSDF-SSGDGSNFCTQWGNPEQEANSRGRG 358
Qy 359 RVIQDAEERPHSRYLRRAYSSDRSGTSNSQSQAKTYTMERCHSAEMLSVSKRSGGGENEE 418
Db 359 RVIEDAEERPHSRYLRRAHSSDRASPSN-QSRAKTYSVERCHSVEMLSKPRRS------- 410
Qy 419 RYSPTDNNANIFNFFKEKTSSSSGSFERPDNNQALSNHLCPGKTPFPFADPTPQTETVQQ 478
Db 411 ----------LDENQHSSNHHCLGKTPFPFADQTPQMEMVQQ 442
Qy 479 WFGNLQINAHLRKTTEYDSISPNRDFQGHPDLQKDTSKNAWTDTKVKKNSDASDNAHSVK 538
Db 443 WFGNLQMNAHLGETNEHHTVSPNRDFQDYPDLQ-DTLRNAWTDTRASKNADTSANVHAVK 501
Qy 539 QQNTMKYMTALHSKPEIIQQECVFGSDPLSEQSKTRGMEPPWGYQNRTLRSITSPLVAHR 598
Db 502 QLSAMKYMSAHHHKPEVMPQEP--GLHPHSEQSKNRSMESTLGYQKPTLRSITSPLIAHR 559
Qy 599 LKPIRQKTKKAVVSILDSEEVCVELVKEYASQEYVKEVLQISSDGNTITIYYPNGGRGFP 658
Db 560 LKPIRQKTKKAVVSILDSEEVCVELLRECASEGYVKEVLQISSDGTMITVYYPNDGRGFP 619
Qy 659 LADRPPSPTDNISRYSFDNLPEKYWRKYQYASRFVQLVRSKSPKITYFTRYAKCILMENS 718
Db 620 LADRPPLPTDNISRYSFDNLPEKYWRKYQYASRFIQLVRSKTPKITYFTRYAKCILMENS 679
Qy 719 PGADFEVWFYDGVKIHKTEDFIQVIEKTGKSYTLKSESEVNSLKEEIKMYMDHANEGHRI 778
Db 680 PGADFEVWFYDGAKIHKTENLIHIIEKTGISYNLKNENEVTSLKEEVKVYMDHANEGHRI 739
Qy 779 CLALESIISEEERKTRSAPFFPIIIGRKPGSTSSPKALSPPPSVDSNYPTRDRASFNRMV 838
Db 740 CLSLESVISEEEKRSRGSSFFPIIVGRKPGNTSSPKALSAPP-VDPSCCKGEQASASRLS 798
Qy 839 MHSAASPTQAPILNPSMVTNEGLGLTTTASGTDISSNSLKDCLPKSAQLLKSVFVKNVGW 898

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Qy        959 LLMFSNPTPNF 969
              ||||||||||||
Db        914 LLMFSNPTPNF 924
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Based on the abstract, the title, and the entire disclosure of the '501, one of skill in the art would not doubt the SAK protein disclosed in the '501 patent is a kinase, and based on the 77% amino acid sequence identity to the SAK polypeptide disclosed in the '501 patent, one of ordinary skill in the art would recognize a polypeptide at least 95% identical to the instant SEQ ID NO:2 would have kinase activity.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues with the attached Manning reference (Appendix A). Applicant argues that Manning reference teaches nearly 10% of all proteins despite having kinase domain homology lacks actual kinase activity. Applicant argues that since the '501 patent did not actually show that the protein possess kinase activity, one of ordinary skill would doubt that the protein disclosed in the '501 patent have kinase activity lacking actual confirmation of biochemical kinase activity.

These arguments have been fully considered but found unpersuasive because one of ordinary skill in the art reading Manning reference would think a protein having a kinase domain homology would likely have biochemical activity because having actual kinase activity has 90% chance vs. 10% chance for not having actual kinase activity. In addition, the '501 patent teaches (column 4 lines 46-55) the following:

> The invention still further provides a method for identifying a substance which is a substrate of the novel serine/threonine kinase protein of the invention, or an isoform or part of the protein, comprising reacting an activated serine/threonine kinase protein of the invention, or part of the protein, preferably the kinase domain, with at least one substance which potentially is a substrate of the kinase protein, or part of the protein, under conditions which permit the phosphorylation of serine/threonine residues, and assaying for phosphorylation of the substance.

Therefore, it would have been obvious for one of ordinary skill to arrive at the claimed invention with a reasonable expectation of success, because the '501 patent teaches an assay to identify a compound for modulating proliferation, especially to treat the various cancers, by determining the kinase activity of a SAK polypeptide, and Tang teaches a SAK polypeptide 99.9% identical (i.e. SEQ ID NO: 2389) to the instant SEQ ID NO:2. One of ordinary skill would have been motivated to make and use the claimed invention to isolate a proliferation-modulating compound for cancer treatment.

Claims 9, 37, and **38** are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,650,501 A of record (22 July 1997) in view of WO

01/53312 A1 of record (Tang) in view of and further in view of US 5,589,356 A (31 December 1996, the '356 patent from now on).

Claims 9, 37, and 38 are interpreted as drawn to method of identifying a useful circular peptide by determining whether or not said circular peptide affecting cellular proliferation when said compound is contacted with a SAK polypeptide.

Applicant argues that the '501 patent does not teach all the limitations of the base claim 9. The argument is fully considered but found unpersuasive for reasons given above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is

571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

/Misook Yu/